MAY 2 2 2014

K133790

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

## 1.0 submitter's information

Name: Andon Health Co., Ltd.

Address: No.3 Jinping Street,Ya'an Road, Nankai District, Tianjin, P.R. China

Phone number: 86-22-6052 6161

Fax number: 86-22-6052 6162

Contact: Yi Liu

Date of Application: 12/03/2013

## 2.0 Device information

Trade name: iHealth BG1 Align Mini Gluco-Monitoring System

Common name: Blood Glucose Monitoring System

Classification name: Blood Glucose Monitoring System

## 3.0 Classification

Production code: NBW- Blood Glucose Monitoring System.
Regulation number: 862.1345
Classification: II
Panel: Clinical Chemistry

Production code: CGA- test, blood glucose, over the counter
Regulation number: 862.1345
Classification: II
Panel: Clinical Chemistry

Production code: JQP- calculator/data processing module, for clinical use.
Regulation number: 862.2100
Classification: I
Panel: Clinical Chemistry

## 4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd.

Device: iHealth BG3 Smart Gluco-Monitoring System

510(k) number: k120813

## 5.0 Device description

The iHealth BG1 Align Mini Gluco-Monitoring System (BGMS) consists of blood glucose meter, single use test strips, sterile lancets, lancing device and the control solutions.

The new device iHealth BG1 is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 5 seconds. The control solution available is used to test the performance of the device. It uses the same technological characteristics for testing with its predicate device.

The appearance of iHealth BG1 is different from the predicate device. Both the iHealth BG1 and the predicate device BG3 need to connect to iOS device to display the rest results, however, iHealth BG1 connect to iOS device through the earphone kack, while BG3 connect to iOS device through the 30-pin dock interface.

## 6.0 Intended use

The iHealth Align Mini Gluco-Monitoring system(BG1) is intended to be used for:

- Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh
- single person measurement only and should not be shared
- Self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control

The iHealth system should not be used for the diagnosis of or screening for diabetes, or for neonatal use.

Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.

iHealth Blood Glucose Test Strips(AGS-1000I) are intended for use with the iHealth Align Mini Glucose meter (BG1) to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealth BG1 meter.

## 7.0 Summary comparing technological characteristics with predicate device

| CHARACTERISTICS | NEW DEVICE: iHealth BG1 Align Mini Gluco-Monitoring System | PREDICATE: iHealth BG3 Smart Gluco-Monitoring System (K120813) |
|---|---|---|
| Indication for Use | The iHealth Align Mini Gluco-Monitoring system(BG1) is intended to be used for:<br>• Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh<br>• single person measurement only and should not be shared<br>• Self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control<br>The iHealth system should not be used for the diagnosis of or screening for diabetes, or for neonatal use.<br><br>Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly. | iHealth BG3 Smart Gluco-Monitoring System is intended to be used for:<br>• quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf or thigh<br>• single person measurement only and should not be shared<br>• self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control<br>The iHealth BG3 Smart Gluco-Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use.<br>Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly. |

| | | |
|---|---|---|
| | iHealth Blood Glucose Test Strips(AGS-1000I) are intended for use with the iHealth Align Mini Glucose meter (BG1) to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealth BG1 meter. | The AGS1000I test strips are intended for use with the iHealth BG3 meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealthBG3 meter |
| Detection Method | Amperometry | Amperometry |
| Enzyme | Glucose Oxidase | Glucose Oxidase |
| Type of Meter | Biosensor (Electrode) | Biosensor (Electrode) |
| Sample Source | Capillary whole blood from AST(Alternative site testing) and finger | Capillary whole blood from AST(Alternative site testing) and finger |
| Sample Application | Blood sample is placed directly to the test strip after finger or AST is lanced. | Blood sample is placed directly to the test strip after finger or AST is lanced. |
| Hematocrit Range | 20-60% | 20-60% |
| Operating Temperature Range | 10℃~35℃(50°-95°F) | 10℃~35℃(50°-95°F) |
| Dimensions | 52mm×30mm×9.5mm | 102mm×58mm ×22mm |
| Display | Connect to iOS device to display measurement results | Connect to iOS device to display measurement results |
| Result Presentation | mg/dL or mmol/L | mg/dL or mmol/L |
| Memory Capabilities | 10000 times with time and date displaying | 10000 times with time and date displaying |
| Test Start | Automatic | Automatic |
| Test Time | 5 second | 5 second |
| Power Source | DC3.0V (CR1620) | DC 3.3V (Powered by iOS device connected to the meter) |
| Battery Life | 200 times testing | N/A |
| Measurement Range | 20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L) | 20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L) |
| Qualified Test Strip | AGS-1000I Test Strip | AGS-1000I Test Strip |
| Sample Volume | Minimum 0.7 micro liter | Minimum 0.7 micro liter |
| Connect Method | Connect to iOS device through Earphone jack | Connect to iOS device through 30-pin dock interface |

## 8.0 Performance summary

The iHealth BG1 Align Mini Gluco-Monitoring System conforms to the following standards:

- ISO 15197: In vitro diagnostic test systems- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

Non-clinical test and the clinical test are done according to the above standard.

## 9.0 Comparison to the predict device and the conclusion

The iHealth BG1 is similar with the predicate device iHealth BG3, the two devices are both for single patient use, they use the same test strip, and can test the blood glucose at the alternative site. The hematocrit range, the altitude and the use function are all the same. The appearance of the two device is different,and both the two devices have no LCD display, they must be connected with iOS device, however, the connect methods are different, BG1 connect to iOS device through earphone jack, while BG3 connect to iOS device through 30-pin dock interface. iHealth BG1 use battery as power source, this is different from the predicate device BG3 which is powered by iOS device connected to the meter.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2014

ANDON HEALTH CO., LTD
MR YI LIU
NO. 3 JIN PING STREET, YA AN ROAD,
NANKAI DISTRICT
TIANJIN, CHINA 300190

Re: K133790
Trade/Device Name: iHealth BG1 Align Mini Gluco-Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JQP
Dated: April 23, 2014
Received: April 25, 2014

Dear Mr. Yi Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled. "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page.*

510(k) Number *(if known)*
k133790

Device Name
iHealth Align Mini Gluco-Monitoring System

Indications for Use *(Describe)*

The iHealth Align Gluco-Monitoring system(BG1) is intended to be used for:
• Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh
• single person measurement only and should not be shared
• Self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control
The iHealth system should not be used for the diagnosis of or screening for diabetes, or for neonatal use.
Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.
iHealth Blood Glucose Test Strips(AGS-10001) are intended for use with the iHealth Align Glucose meter (BG1) to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealth BG1 meter.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck -S